REMARKS

Prior to entering this amendment, Claims 1-8 and 10-29 were pending in the application. Claims 11-13 and 15-29 were withdrawn from consideration.

Claims 1 and 14 are amended to clarify the selecting step which now defines:

"selecting for the dual transgenic plant by identifying plants, or portions thereof which:

(a) are deficient in the tag protein;

(b) are deficient in expression of the first coding region; or

(c) have an identifiable genotype or phenotype of the dual transgenic plant associated with being deficient in the tag protein or deficient in expression of the first coding region."

Claims 11-13 and 15-29 are cancelled as drawn to non-elected invention. Applicants reserve the rights to file one or more divisional applications directed to the cancelled claims.

No new matter is added in the above amendment. Examiner is requested to enter the amendment and reconsider the application.

CLAIM REJECTIONS - 35 USC § 112, Second Paragraph

6. Claims 1-8 and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Examiner states that in claim 1, the recitation, "expression of the first coding region" in part iv), renders the claim indefinite. Examiner alleges that it is unclear whether selection is due to the expression or the deficiency of expression of the first coding region.

Claim 1 has been amended to give the recitation "are deficient in expression of the first coding region" to clarify claim 1.

Examiner states that in claim 1 the recitation "an identifiable genotype type or phenotype of the dual transgenic plant associated therewith", renders the claim indefinite as it is unclear what the recitation encompasses.

Claim 1 has been amended to give the recitation "have an identifiable genotype or phenotype of the dual transgenic plant associated with being deficient in the tag protein or deficient in expression of the first coding region" to clarify claim 1.

In view of the above comments and foregoing amendments, Examiner is respectfully requested to withdraw the rejection of claims 1-8 and 10 as being indefinite under 35 U.S.C. 112, second paragraph.

CLAIM REJECTIONS - 35 USC § 112, First Paragraph

7. Claims 1, 3, 5-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. Examiner states that the claims(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, Examiner states that the genus of tag proteins encompasses any tag protein, any reporter, any enzyme or any antibody, however, the specification does not describe any antibody that can be used to practice the invention. Further Examiner states that the specification also does not describe any other reporter protein, enzyme other than GUS protein or any other conditional lethal gene other than iaaH coding region. Examiner alleges, that the specification does not correlate any structure of reporter protein, enzyme, antibody or conditional lethal coding region with the function of a tag protein, therefore, given the breadth of the claims and the lack of enough description, a person skilled in the art would conclude that applicant is not in possession of the claimed invention.

Applicants respectfully traverse the rejection.

The term "tag protein" is specifically defined at page 20, lines 1 to 16 of the specification as filed as follows:

> "By the term "tag protein" it is meant any protein that is capable of being identified in a plant. For example, but not wishing to be limiting, the tag protein may be an enzyme that catalyzes a reaction, for example GUS. In such an embodiment the enzyme may be identified by an enzymatic assay. Alternatively, but without wishing to be limiting, the tag protein may be an immunogen and identified by an immunoassay, or the tag protein may confer an observable phenotype, such as, but not limited to the production of green fluorescent protein (GFP). Other methods for the detection of the expression of the first coding region (30) may be used, including but not limited to, Northern hybridization, S1 nuclease, array analysis, PCR, or other methods as would be known to one of skill in the art. The tag protein may also be a positive selection marker, for example, a conditionally lethal protein which is encoded by a conditionally lethal sequence (the first coding region), resulting in an observable phenotype, for example wilting or death of a plant or a portion thereof. Non-limiting examples of constructs comprising a first coding region (30) encoding a tag protein (35) include constructs listed in Table 2 (see Examples) and in Figure 9 A (p74-316; p74-118; p74-117; p74-

501), Figure 9B (p74-315), Figure 9C (p74-309), Figure 9D (p74-508), and Figure 11 (p74-110, p74-114)."

The present invention as claimed is directed to a method of selecting for a plant that comprises a coding region of interest, the plant being transformed with (1) a first nucleotide sequence comprising an operator sequence and a first coding region encoding a tag protein and (2) a second nucleotide sequence encoding a repressor and a coding region of interest. If both the first and second nucleotide sequences are present in the transformed plant then the coding region for the repressor protein on the second nucleotide will be expressed to produce the repressor protein which will bind to the operator sequence of the first nucleotide sequence, thereby reducing or inhibiting expression of the first coding region encoding the tag protein. Dual transgenic plants that comprise the coding region of interest can therefore be selected by identifying plants that are deficient in tag protein or are deficient in expression of the first coding region. As disclosed at page 23, line 28 to page 24, line 5 of the specification as filed:

> "In this way selecting may be used to differentiate between a plant which lacks the second nucleotide sequence (50) comprising the coding region of interest (70), and the third gene that encodes the repressor (90) from a plant that expresses the second nucleotide sequence (50), since if the repressor is present, then the repressor binds the operating sequence (40) of the first nucleotide sequence (10), and inhibits or reduces expression of the first coding region (30), and tag protein levels are reduced. Conversely, if the tag protein is present, then visual inspection of the plant or portion thereof indicates either that the first nucleotide construct has been introduced into the plant, as in i) above, or that the plant or portion thereof has not been transformed with the second nucleotide sequence, as in ii) above."

Therefore, any type of tag protein may be used - what is required for the method of the invention is that the "tag protein" is a protein capable of being identified in a plant as outlined in the description (see above).

Applicants submit that the meaning of the word "tag protein" would be evident to one skilled in the art upon reading of the description and would be readily able to identify which type of proteins could be used and would be suitable as a "tag protein" (i.e. a protein capable of being identified in a plant). Furthermore, the description provides several examples of suitable tag proteins including an enzyme that catalyzes a reaction such as GUS, an immunogen identified by an immunoassay, a protein that confers an observable phenotype, such as green fluorescent protein (GFP), a positive selection marker such as a conditionally lethal protein resulting in an observable phenotype like wilting or death of a plant. At the time the application was filed (namely November 21, 2003), coding regions for these types of "tag proteins" were routinely being transformed into plants to provide a readily identifiable

marker in plant transformation. A person of skill in the art would therefore conclude that applicant was in possession of the claimed invention at the time the application was filed.

As stated in LizardTech, Inc. v. Earth Resource Mapping, PTY, Inc.(424 F.3d 1336, 1345 (Fed. Cir. 2005) (citing Union Oil Co. v. Atl. Richfiled Co., 208 F. 3d 989, 997 (Fed. Cir. 2000); In reGPAC Inc., 57 F. 3d 1573, 1579 (Fed. Cir. 1995)):

> "A claim will not be invalidated on section 112 grounds simply because the embodiments of the specification do not contain examples explicitly covering the full scope of the claim language. That is because the patent specification is written for a person of skill in the art, and such a person comes to the patent with the knowledge of what has come before. Placed in that context, it is unnecessary to spell out every detail of the invention in the specification; only enough must be included to convince a person of skill in the art that the inventor possessed the invention and to be enable such a person to make and use the invention without undue experimentation."

Applicant submits that they need not exemplify every variant of what a tag protein may be, since the use of such proteins is well known in the art.

Examiner cites Federal Circuit decision *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997) and states that a written description of an invention "requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other material" and that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material". Examiner also states that the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to "visualize or recognize the identity of the members of the genus".

In the *University of California v. Eli Lilly and Co.* the patentee's original application disclosed DNA sequence encoding for rat proinsulin but claimed plasmids and microorganisms with DNA encoding for the vertebrate genus and human species, which were held to violate the description requirement. The court stated "[w]e must decide whether the isolation and characterization of one species allows the inventor to claim the genera in which that species is a member, as well as other species from those genera" and found that "the isolation and characterization of the proinsulin cDNA from one member of a genus is not sufficient to support claims to the insulin cDNA of thousands of other species from that genus".

This is very different from the present application which claims a method of selecting for a plant comprising a coding region of interest, the plant being transformed with a first nucleotide sequence comprising an operator sequence and a first coding region encoding a tag protein and a second nucleotide sequence encoding a repressor and a coding region of interest. The tag protein is any protein identifiable in a plant to enable selection of a dual transgenic plant. Applicants are not claiming isolation and characterization of a new genus. They are not claiming the "tag protein" *per se*, or claiming exclusive rights to the specific use of "tag proteins", instead Applicants are claiming a method which uses amongst other things a nucleotide sequence which encodes a tag protein as a means of identifying if a plant has been transformed with a coding region of interest. Applicants respectfully submits that the claims of present application are very different from the claims of the granted patent being disputed in *University of California v. Eli Lilly and Co.* and that the findings of this case are therefore not applicable for the present application.

Claims 9, 11-13, 15-18 are cancelled. In view of the above comments, Examiner is respectfully requested to withdraw the rejection of claims 1, 3, 5-8, 10, 14 under 35 U.S.C. 112, first paragraph for failing to comply with the written description requirement.

8. Claims 1, 3, 5-18 are rejected under 35 U.S.C. 112, first paragraph, because the specification while being enabling for GUS gene and iaaH gene as tag protein, does not reasonably provide enablement for any reporter gene, any tag protein, or any reporter, or any enzyme, or any conditional lethal gene. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Specifically, Examiner states that the claim encompass any reporter gene, any tag protein, or any reporter, or any enzyme, or any conditional lethal gene and that the specification only provides guidance on GUS protein and iaaH coding region as tag proteins. Examiner alleges that since most of those tag proteins are from organisms other than plant, without further guidance, for each tag protein, for example a conditional lethal gene, a person skilled in the art would have to test its functionality in plant and the conditions suitable for selection. Therefore undue experimentation would be required to practice the invention in full scope given unmanageable numbers of combinations of tag proteins and plant species involved. In summary, given the claim breadth, lack of further guidance and additional

working example, unpredictability of the art, undue experimentation would be required for person skilled in the art to practice the invention.

Applicants respectfully traverse the rejection.

As mentioned above, the use of a tag protein is known in the art.. Therefore, there is no need to exemplify every embodiment of what is known within the art. Applicants submit that the meaning of the word "tag protein" would be evident to one skilled in the art upon reading of the description and would be readily able to identify which type of proteins could be suitable as a "tag protein" (i.e. a protein capable of being identified in a plant) and used within the "first nucleotide sequence". Furthermore, the description provides several examples of suitable tag proteins including an enzyme that catalyzes a reaction such as GUS, an immunogen identified by an immunoassay, a protein that confers an observable phenotype, such as green fluorescent protein (GFP), a positive selection marker such as a conditionally lethal protein resulting in an observable phenotype like wilting or death of a plant. Use of these "tag proteins" in plant transformation was routine at the time the application was filed, and may be obtained from a variety of sources. A skilled person would be able to identify and use different tag proteins without under experimentation.

Applicants respectfully submit that if this invention was in the mechanical arts and the claim defined, for example, a method of optically reading bar coded data comprising, amongst other things, providing a light source and a list of light sources were provided, and a specific source exemplified, the Applicant would not be limited to the light source being an LED merely because that was the only light source specifically exemplified. If any type of light source may be used in the method, then the Applicant should be entitled to claim any light source. Applicant submits that in the present invention, any type of tag protein may be used in the invention, therefore to limit the specific tag protein to those exemplified would unfairly limit the scope of the claims.

The Court in *Chiron Corp. v. Genentech. Inc.*, 363 F.3d 1247, 70 USPQ2d 1321 (Fed. Cir. 2004), *cert.deinied*, 543 U.S. 1050 (2005), applying the enablement requirement, concocted a "knowledge continuum" distinguishing among (1) "routine technology" which need not be disclosed, (2) technology "arising after the date of the application, which also need not be disclosed, such disclosure being impossible, and (3) "nascent technology" which, must be disclosed. The Court held "[A] patent disclosure need not enable information within the knowledge of an ordinarily skilled artisan. Thus, a patentee preferably omits from the disclosure any routine technology that is well know at the time of application." 363 F.3d at

1254. Tag proteins were routinely used in plant transformation by ordinarily skilled artisans at the time the application was filed and therefore the use of tag proteins falls in the category of "routine technology", which, according to the Court in *Chiron Corp.* need not be disclosed.

Claims 9, 11-13, 15-18 are cancelled. In view of the above comments, Examiner is respectfully requested to withdraw the rejection of claims 1, 3, 5-8, 10, 14 under 35 U.S.C. 112, first paragraph for failing to comply with the enablement requirement.

CLAIM REJECTIONS – 35 USC § 102(b)

9. Claims 1-4 and 14 are rejected under 35 USC 102(b) as being anticipated by Wilde et al. (1992, The EMBO Journal 11:1251-1259).

Examiner states that Wilde et al. teach that transgenic tobacco plant, CAB-gus #R1A, comprising the plasmid pJC5/BIN, which comprises the GUS gene (the first coding region) under the control of lac operator, was produced (page 1255, 3rd and 4th paragraphs of the left column; also Figure 7A) and that the plasmid pJC19 containing the repressor expression cassette with the lacI gene (the third coding region) under the control of caMV 35S promoter, and hygromycin-resistance selectable marker (the second regulatory and coding region), was introduced into CAB-gus # R1A plant (page 1255, 5th paragraphs of the left column; also Figure 7B). Examiner goes on to state that dual transgenic plants were obtained by selecting on hygromycin medium (page 1258, 6th paragraph of left column) and show reduced GUS activities (Figure 8). It is alleged by Examiner, given that selecting for dual transgenic plant is done by an identifiable phenotype (hygromycin resistance) of the dual transgenic plant associated therewith, the reference teaches all the limitations set forth by the claims.

Applicants respectfully disagree.

Wilde discloses a dual construct system that requires the use of antibiotic selectable markers on each of the constructs to determine whether the gene of interest is expressed in a plant. Figure 7A shows that plasmid pJC5/BIN comprises Kan^r conferring kanamycin resistance in *E. coli*, and Neo^r for conferring kanamycin resistance in plants, and plasmid pJC19 comprises Kan^r for *E coli* selection, and Hyg^r for selection in plants. The problem associated with the use of antibiotic selection, is what the present invention is addressing (see for example page 7, lines 23-30).

Wilde et al. investigated the efficacy of using the *Escherichia coli lac* operator – repressor system to control plant gene expression. There is no hint or suggestion in Wilde et

al. of a method of selecting for a plant that comprises a coding region of interest using the lac operator – repressor system. Examiner states that the hygromycin-resistance selectable marker is the second regulatory and coding region of the present invention. The present claims define that the second coding region comprises a coding region of interest. The coding region of interest is defined on page 34, line 19 to page 35 line 15. For example, as disclosed at page 34, lines 19-25 of the specification:

> "By "coding region of interest" it is meant any nucleotide sequence that is to be expressed within a plant cell, tissue or entire plant. A coding region of interest may encode a protein of interest such as, but not limited to an industrial enzyme, protein supplement, nutraceutical, or a value-added product for feed, food, or both feed and food use. Examples of such proteins of interest include, but are not limited to proteases, oxidases, phytases, chitinases, invertases, lipases, cellulases, xylanases, enzymes involved in oil biosynthesis, etc."

The hygromycin-resistance selectable marker is therefore not a coding region of interest in accordance with the present invention. The selectable marker is used to determine that the plant has been successfully transformed with the associated nucleotide sequence. Therefore, the hygromycin-resistance selectable marker is analogous to the tag protein within the first nucleotide sequence, rather than a coding region of interest within the "second nucleotide sequence".

Examiner also states that given that selecting for dual transgenic plant is done by an identifiable phenotype (hygromycin resistance) of the dual transgenic plant associated therewith, the reference teaches all the limitations set forth by the claims. Claims 1 and 14 define that selecting for the dual transgenic plant is done by identifying plants which have an identifiable genotype or phenotype of the dual transgenic plant associated with being deficient in the tag protein or deficient in expression of the first coding region. Examiner suggests that the GUS gene of Wilde et al. is the first coding region, and therefore selection of hygromycin resistance is not identifying plants that are deficient in the tag protein or deficient in expression of the first coding region. Therefore, Wilde et al. does not teach the selecting step defined in amended claims 1 and 14, thus claims 1 and 14 are not anticipated by Wilde et al. Claims 2-4 are dependent on claim 1 and are therefore not anticipated by Wilde et al. at least in view of their dependency.

In view of the above comments, Examiner is respectfully requested to withdraw the rejection of claims 1-4 and 14 under 35 U.S.C. 102(b) as being anticipated by Wilde et al.

10. Claims 1-4 and 14 are rejected under 35 USC 102(b) as being anticipated by Cigan et al. (U.S. Patent No. 6,399,856).

Examiner states that Cigan et al. teach a method for producing reversible male sterility in maize plant, comprising the steps of: (a) providing a first plant which is male sterile, said plant having a first genetic construct, said first genetic construct comprising (i) an operator that is capable of controlling expression of a dominant negative gene, (ii) a dominant negative gene, such as DAM Methylase, that, when expressed in a plant, disrupts pollen formation or function, (iii) a first gene encoding a first DNA binding protein which can bind to the operator and activate transcription of said dominant negative gene, and (iv) a first promoter that drives transcription in cells critical to pollen formation or function, said first promoter regulating the transcription of said first gene encoding said first DNA-binding protein; (b) providing a second plant which is male fertile, said second plant having a second genetic construct comprising a suitable second promoter controlling a second gene encoding a second DNA-binding protein, said second DNA-binding protein interacting with the operator of the first genetic construct, such that the transcription of the dominant negative gene is repressed; and (c) crossing said first plant with said second plant to form a hybrid plant which is male fertile (claim 1; also Examples 4 and 8).

Examiner alleges given that the male fertility is an identifiable phenotype associated with dual transgenic plant, that the second nucleotide sequence of instant claim is introduced by crossing, and that any gene on the chromosome linked to the repressor expression cassette, such as bar gene (Figure 14) can be regarded as second coding and regulatory regions, i.e. gene of interest, the reference teaches all the limitations set forth by the instant claims.

Applicants respectfully disagree.

Cigan et al. relates to the use of dominant negative genes and an anther-specific promoter, where male sterility is reversed by incorporating into a plant a second genetic construct which represses the dominant negative gene. There is no hint or suggestion in Cigan et al. of a method of selecting for a plant that comprises a coding region of interest as is claimed in the present invention.

Examiner states that any gene on the chromosome linked to the repressor expression cassette, such as bar gene (Figure 14) can be regarded as second coding and regulatory regions, i.e. gene of interest. However, this is incorrect as the claims of the present invention define that the second coding region comprises a coding region of interest and not a selectable marker. The definition of the coding region has been provide above.

Applicant submits that the Cigan et al. only discloses selectable marker genes, such as the bar gene (or the PAT gene), on the DNA construct comprising the repressor gene (e.g. plasmids PHP6522, Figure 13; PHP6555, Figure 14) or within the sterility construct (PHP6520, Figure 15, PHP8036, Figure 16; PHP8037, Figure 17). Selectable markers are not a coding region of interest in accordance with the present invention but are instead markers used to select if the plant has been successfully transformed. If Examiner is suggesting that the BAR (or PAT) gene is a coding region of interest, then both of the constructs used by Cigan et al. in the dual transgenic plants in Example 8 comprise coding a region of interest, and there is no need for the expression of repressor to repress expression of the tag protein. The combination of elements in the constructs disclosed in Cigan et al. are different than those defined in claims 1 and 14 of the present invention.

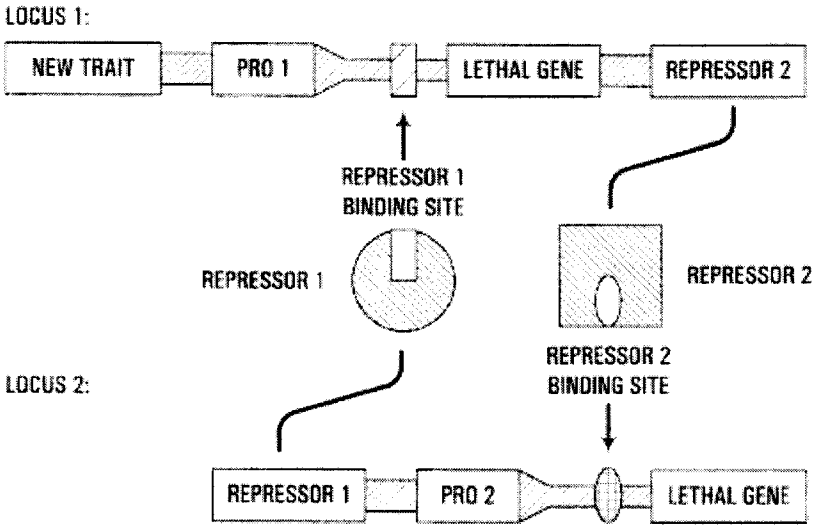
Claims 1 and 14 are therefore not anticipated by Cigan et al. Claims 2-4 are dependent on claim 1 and are therefore not anticipated by Cigan et al., at least in view of their dependency.

In view of the above comments, Examiner is respectfully requested to withdraw the rejection of claims 1-4 and 14 under 35 U.S.C. 102(b) as being anticipated by Cigan et al.

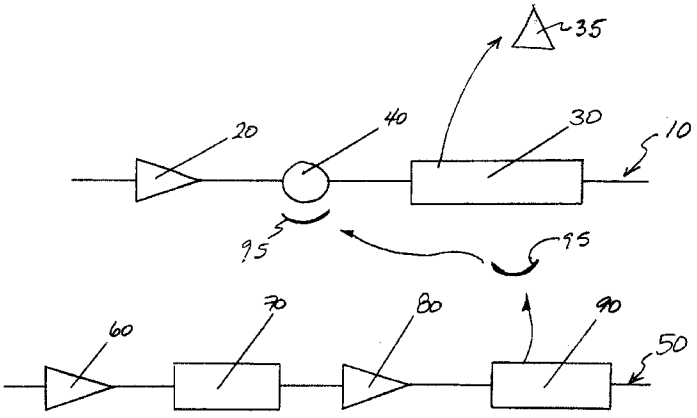
CLAIM REJECTIONS - 35 USC § 103(a)

12. Claims 1-10 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fabijanski et al. (US Patent No. 6,753,460) in view of Mason et al. (1992, *PNAS* 89:11745-11749) and Chou et al. (1998, *PNAS* 95:5293-5298). Applicant respectfully traverses the rejection.

Examiner states "Fabijanski et al. teach DNA constructs of Figure 3, wherein locus 2 (corresponding to first nucleotide sequence in the instant claims) containing a lethal gene (corresponding to tag gene) under the control of a modified repressible promoter, Pro2 (corresponding to first regulatory region), and wherein locus 1 (corresponding to second nucleotide sequence in the instant claims) containing a repressor gene, repressor 2 (corresponding third coding region) under the control of a modified repressible promoter, Pro1 (corresponding to third regulatory region) and new trait gene expression cassette (corresponding to second coding and regulatory regions)." Figure 3 is reproduced below:



Applicants respectfully submit that the DNA constructs of Figure 3 are different from the first and second nucleotide sequence of the present claims. In particular, there is no hint or suggestion in Fabijanski et al. that the gene encoding a new trait (corresponding to the second coding region e.g. "70", in Figure 2 of the present application) in locus 1 of Figure 3 is in operative associate with a regulatory region (second regulatory region, e.g. "60" of the present application) which is separate to the regulatory region (third regulatory region, e.g. "80" of the present application) in operative association with the repressor 2 gene (third coding region, e.g. "90" of the present application). Figure 2 of the present invention is shown below for comparison:



In other words, the second nucleotide sequence of the present invention as claimed comprises a second regulatory region in operative association with the second coding region (coding region of interest) and a separate third regulatory region in operative associate with a third coding region (repressor gene), whereas locus 1 of Figure 3 taught by Fabijanski et al., only has one regulatory region (Pro1) which is operatively linked to the gene for the new trait, the lethal gene and the repressor 2 gene. Throughout Fabijanski et al. it is taught that the gene for the novel trait is linked to the repressible lethal gene to ensure that the novel trait can not persist in related species by transfer through sexual crossing (for example at column 7, lines 36-38 of Fabijanski et al.). This arrangement is not found in the present invention.

There is no hint or suggestion in Fabijanski et al. that the gene for the novel trait may be under the control of a separate regulatory region to the regulatory region which controls expression of the lethal gene. Utilization of a second regulatory region in operative association with the coding region of interest and a separate third regulatory region in operative association with the repressor gene, results in optimal expression of the coding region of interest and the repressor in the method of the present invention.

Furthermore, both constructs in Fabijanski et al. encode a repressor and they both encode a lethal gene product. As stated on page 4, lines 5-11 of the present application, with reference to the PCT counterpart application (WO 0037660):

> "A drawback of the application is that the repressor must be expressed in order to have the coding region of interest expressed. Failure to express the repressor results in expression of the lethal gene and causes the death of the plant."

With the method of the present invention, there is no need to express a repressor on both constructs.

There is no teaching in Fabijanski et al. of how the DNA constructs shown in Figure 3 actually operates. It is stated that "[i]n another preferred embodiment, DNA constructs are introduced into a plant cell, comprising two repressible lethal genes and two functionally distinct repressors for the repressible lethal genes. The genes are preferably arranged so that the first repressible lethal gene is linked to the repressor capable of repressing the second repressible lethal gene, and the second repressible lethal gene is linked to the repressor capable of repressing the first repressible gene, as illustrated in FIG. 3." (see column 7, lines 52-60 of Fabijanski et al.). If both locus 1 and locus 2 are co-expressed in a plant, this results in expression of repressor 1 which will bind to repressor 1 binding site on locus 1 thereby

inhibiting or reducing expression of the lethal gene. This will also result in repressing expression of repressor 2. If no repressor 2 is expressed, then the lethal gene on locus 2 will be expressed and the plant will die. The same is true if the repressor from locus 1 is expressed first. While expression if the lethal gene on locus 2 is repressed, so is expression of repressor 1. This leads to expression of the lethal gene on locus 1 and the plants will die.

Examiner alleges that it would have been obvious and within the scope for a person with ordinary skill in the art to modify the method of Fabijanski et al. by using the expression cassette of Mason et al. as a new trait in construct containing locus 1 of Fabijanski et al. Applicants respectfully disagree.

Mason et al. teach transgenic tobacco plants expressing the hepatitis B surface antigene under the control of CaMV 35S promoter. There is no hint or suggestion in Mason et al. that the expression cassette comprising a gene encoding hepatitis B surface antigen linked to a CaMV 35S promoter would be used as a new trait in construct containing locus 1 of Fabijanski et al.. Furthermore, there is no teaching or suggestion to introduce additional elements (e.g. the repressor or operator elements) in the construct disclosed in Mason et al. Nor is there any teaching or suggestion of using two constructs.

Examiner alleges "[o]ne would have been motivated to do so given the teaching of Mason et al. that hepatitis B surface antigen could be used as a vaccine against hepatitis B virus infection". While Applicant agrees that the hepatitis B surface antigen may be used as a coding region of interest within the constructs of the present invention, and within Fabijanski et al., there is no teaching in Mason that would suggest that the antigen would be inserted within locus of Fabijanski et al. under the control of a second promoter. At the time that Fabijanski et al. presented their invention, constructs comprising a coding region of interest under the control of a promoter as proposed by Mason et al. were well known within the art, yet Fabijanski et al do not include such constructs within their locus 1 construct.

The combination of Mason et al. with Fabijanski et al. would not have lead one of skill in the art to obtain the constructs as used in the present invention as the "new trait" on locus 1 would be replaced with the hepatitis B antigen, and the construct would not comprise a second regulatory region in operative association with the coding region of interest and a separate third regulatory region in operative association with the repressor gene.

In order to set forth a prima facie case of obviousness under 35 U.S.C. 103(a), the combination of the cited references must actually teach or suggest the claimed invention.

Applicants respectfully submit that if Mason et al. and Fabijanski et al. are combined, the skilled person would still not arrive at the claimed invention.

Examiner also alleges that it would also have been obvious for a person with ordinary skill in the art to modify the repressible phaseolin promoter of Fabijanski et al. by replacing the tet operator with the Ros operator of Chou et al. and cross the transformed tobacco carrying a repressible lethal gene under the control of a modified phaseolin promoter with tobacco that was transformed with a gene encoding a Ros repressor.

As stated by Examiner, Chou et al. teach the zinc finger gene from *Agrobacterium*, Ros, and repression of the virC/D and ipt genes by binding of Ros to the conserved operator "ros box". Applicants respectfully submit that even if a combination of Fabijanski et al. and Chou et al. is made, and the tet operator of the phaseolin promoter of Fabijanski et al. were replaced with the Ros operator of Chou et al, the skilled person would still not arrive at the claimed invention. There resulting DNA construct would still not comprise a second regulatory region in operative association with the coding region of interest and a separate third regulatory region in operative association with the repressor gene.

Only the present invention teaches a method of selecting for a plant or portion thereof that comprises a coding region of interest, where the coding region of interest and its associated regulatory region are on the second nucleotide sequence together with a coding region encoding a repressor and its separate associated regulatory region. Neither Mason et al., Fabijanski et al. nor Chou et al. hint or suggest such a method. "To imbue one of ordinary skill in the art with knowledge of the invention in suit, when no prior art reference or references of record convey or suggest that knowledge, is to fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher" *W.L. Gore & Associates, Inc. v. Garlock Inc.*, 721 F.2d 1540, 1553, 220 USPQ 303, 312-13 (Fed. Cir. 1983). Applicants respectfully submit that Examiner has only arrived at the present invention from the combination of Fabijanski et al., Mason et al. and Chou et al. through the benefit of impermissible hindsight.

Claims 2-10 ultimately depend from claim 1 and include the limitations thereof. Therefore, Examiner has failed to set forth a *prima facie* case of obviousness for claims 1-10 and 14. Applicants respectfully request that the rejection be reconsidered and withdrawn.

CLAIM REJECTION-Provisional Double Patenting

12. Claims 1-8, 10 and 14 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over claims 18-24 of copending Application No. 10/719,996 in view of Mason et al. (1992, *PNAS* 89:11745-11749).

Applicants wish to postpone the response to this provisional rejection until the claims are otherwise allowable.

13. Claims 1-8, 10 and 14 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 18, 21 and 24 of copending Application No. 10/995,951 in view of Mason et al. (1992, *PNAS* 89:11745-11749).

Applicants wish to postpone the response to this provisional rejection until the claims are otherwise allowable.

CONCLUSION

In view of the above, examination of the application on the merits and allowance is respectfully requested.

Respectfully submitted,

Date: November 29, 2007

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